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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,914	09/25/2003	Brian B. Lentrichia	2024738-7030290000 (11.02	9190

7590 08/10/2005

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EXAMINER	
HINES, JANA A	
ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 08/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/672,914	LENTRICHIA, BRIAN B.	
	Examiner	Art Unit	
	Ja-Na Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 September 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-25* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Claims 1-2, 6 and 14-19 are generic to a plurality of disclosed patentably distinct species comprising:

Species I (claims 3-5) is drawn to the sensor comprising an antibody, polynucleotide or peptide nucleic acid.

Species II (claims 7-13) is drawn to the target being a cell surface molecule, soluble molecule, membrane bound, DNA, RNA, a pathological organism or a viral marker.

Species III (claims 20-25) is drawn to the agent is a chromophore, lumiphore, fluorophore, chromogen, hapten, antigen, radioactive isotope, magnetic particle, metal nanoparticle, enzyme, antibody or binding portion or equivalent thereof, aptamer, and one member of a binding pair.

2. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Patentably Distinct Species

3. Species I. The plurality of disclosed species are patentably distinct because antibodies comprises 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs) that function to bind an epitope. Polynucleotides are composed of purine and pyrimidine units, and are structurally distinct molecules wherein the polynucleotide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to a primary amino acid sequence. A peptide nucleic acid (PNA) are DNA mimics with a pseudopeptide backbone. PNA is an extremely good structural mimic of DNA (or RNA), and PNA oligomers are able to form very stable duplex structures with Watson-Crick complementary DNA; RNA (or PNA) oligomers, and they can also bind to targets in duplex DNA by helix invasion. Thus the antibody, polynucleotide, and peptide nucleic acid are structurally distinct molecules. The antibody, polynucleotide, and peptide nucleic acid as determined by their different structure and associated functions are patentably distinct, each from the other. And one sensor is not required to practice the invention with another. Each sensor comprises separate and distinct functions that do not share a substantial structural feature disclosed as being essential to the utility of the invention.

Species II. The plurality of disclosed species are patentably distinct because the target is a cell surface molecule, soluble molecule, membrane bound, DNA, RNA, a pathological organism or a viral marker. Cell surface molecules are cell surface

proteins that bind signalling molecules external to the cell with high affinity and convert this extracellular event into one or more intracellular signals that alter the behavior of the target cell. Soluble molecule describes the form of the molecule. DNA is a deoxyribonucleotide polymer that is the primary genetic material of all cells including eukaryotic and prokaryotic organisms, yet several important biological processes transiently involve single-stranded regions. DNA consists of a polysugar-phosphate backbone possessing projections of purines and pyrimidines and forms a double helix that is held together by hydrogen bonds between these purines and pyrimidines. RNA is a polynucleotide consisting essentially of chains with a repeating backbone of phosphate and ribose units to which nitrogenous bases are attached. RNA is unique among biological macromolecules in that it can encode genetic information, serves as an abundant structural component of cells, and also possesses catalytic activity. A pathological organism encompasses pathogenic bacteria, viruses and fungi. A viral marker comprises measurable and quantifiable biological parameters (e.g., specific enzyme concentration, specific hormone concentration, specific gene phenotype distribution in a population, presence of biological substances) which serve as indices for health- and physiology-related assessments, such as disease risk, psychiatric disorders, environmental exposure and its effects, disease diagnosis, metabolic processes, substance abuse, pregnancy, cell line development and epidemiologic studies. One target is not required to practice the invention with another. Each target comprises separate and distinct functions that do not share a substantial structural feature disclosed as being essential to the utility of the invention.

Species III. The plurality of disclosed species are patentably distinct because Because the methods rely upon an agent which is a chromophore, lumiphore, fluorophore, chromogen, hapten, antigen, radioactive isotope, magnetic particle, metal nanoparticle, enzyme, antibody or binding pair. A chromophore is a p-hydroxybenzylidene-imidazolidone which consists of residues 65-67 (Ser-*dehydro*Tyr - Gly) of the protein and the cyclized backbone of these residues forms the imidazolidone ring. A lumiphore, is a detection system based on lanthanide fluorescence complexes. A fluorophore is a single dye fluorescent molecule while a chromogen is a compound that can be converted to a pigment. A hapten is a small antigenic determinants but by themselves cannot elicit an antibody response. An antigen is a substance that is recognized by the immune system and induce an immune reaction. Radioactive isotope are isotopes that exhibit radioactivity and undergo radioactive decay. Magnetic particles are simultaneously exposed to a time-constant magnetic field of sufficiently large magnitude, the particle magnetization becomes saturated and the generation of harmonics is suppressed. While metal nanoparticle are metallic nanometer-sized objects. Enzymes are biological molecules, usually proteins, that possess catalytic activity which may occur naturally or be synthetically created. Antibodies are immunoglobulin molecules having a specific amino acid sequence by virtue of which they interact only with the antigen that induced their synthesis in cells of the lymphoid series or with an antigen closely related to it. Finally, a binding pair is a first and second pair of molecules which specifically bind to each other with great affinity. One agent is not required to practice the invention with another. Each agent comprises separate and

distinct functions that do not share a substantial structural feature disclosed as being essential to the utility of the invention.

It is noted that if an enzyme is selected then claims 21 and 25 will examined; or if fluorophore is selected then claims 22-24 will be examined;

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
August 3, 2005